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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/252,710	06/02/94	RIVIERE	5141113

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PENNIE & EDMONDS
1155 AVENUE OF THE AMERICAS
NEW YORK NY 10036-2711

EXAMINER	
FREEDMAN, J	
ART UNIT	**PAPER NUMBER**
1809	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 08/252,710	Applicant(s) Riviere et al
	Examiner Jeffrey Fredman	Group Art Unit 1809

☒ Responsive to communication(s) filed on *Sep 18, 1997* .

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-4, 6-31, and 35-41* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-4, 6-31, and 35-41* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Double Patenting

1. The non-statutory double patenting rejection, whether of the obvious-type or non-obvious-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornam*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 (b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78 (d).

Effective January 1, 1994, a registered attorney or agent of record may sign a Terminal Disclaimer. A Terminal Disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-4, 6-8, 38 and 39 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of copending application Serial No. 08/486,858. Although the conflicting claims are not identical, they are not patentably distinct from each other because the vectors claimed in the copending application contain essentially the same components as those claimed in the instant application.

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

4. Claims 1-4, 6-8, 20, 21 and 35-39 are rejected under 35 U.S.C. § 103 as being unpatentable over Temin in view of Bender et al. and Cone et al. Temin teaches the construction of various defective recombinant retroviral vectors based on murine leukemia viruses. These vectors can express a gene of interest, which may be virtually any gene because, as noted at page 163, there "are no reports of genes that cannot be expressed in retrovirus vectors." Helper cells transduced with these vectors are taught on page 156 of Temin. Temin further teaches that retroviral vectors may employ splice donor and acceptor sites (see page 162, constructs 5-7).

Temin also teaches that stocks of helper-free virus may be prepared from vectors that do not have a selectable marker if the vectors are cotransfected into helper cells with a plasmid containing a selectable marker. Bender teaches that the packaging signal of vectors based on the Moloney murine leukemia virus extends into the gag region. Applicant claims vectors in which a splice donor and a splice acceptor are included, as well as an additional portion of the gag gene to enhance packaging. Cone et al. teach the construction of helper-free recombinant retroviral vectors and note on page 6353 that:

> "...one can readily isolate lines such as Ψ-AM2275 that produce $>10^5$ recombinant virus per ml. These titers are high enough to facilitate the nonselective introduction of genes into 100% of a population of cells at high enough cell numbers to allow rapid analysis of DNA, RNA, or protein."

The claims are drawn to vectors that have splice donor and acceptor sites located between a 5' LTR and a 3' LTR and do not contain complete *gag, pol* or *env* genes or a complete selectable marker. One of ordinary skill in the art would have known from the combined teachings to make recombinant retroviral vectors that lack a complete selectable marker since the selectable marker gene would be unnecessary in view of the teaching of Cone et al. Cone provides specific motivation to perform transduction without a selectable marker stating "These titers are high enough to facilitate the nonselective introduction of genes into 100% of a population of cells at high enough cell numbers to allow rapid analysis of DNA, RNA, or protein (page 6353, column 1, paragraph 2)". This statement represents express motivation to perform nonselective transduction in order to permit rapid analysis of DNA, RNA or protein without necessitating the use of

chemicals which might alter the experimental system. Further, Bender states "We conclude that the retrovirus packaging signal extends into the gag region. We have found that retroviral vectors containing the complete packaging signal allow more efficient gene transfer into a variety of cell types (page 1639, abstract)". The combined teachings of the prior art of Temin, Cone and Bender would have suggested such modifications to known vectors in the art as a means of regulating gene expression and increasing the efficiency of vector packaging. Therefore, the invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

5. Claims 2-4 and 20 are rejected under 35 U.S.C. § 103 as being unpatentable over Temin in view of Cone et al. as applied to claims 1, 6-8, 20 and 21 above, and further in view of Bender et al. Bender et al. teach that the packaging signal of vectors based on Moloney murine leukemia virus extends into the *gag* region. Claims 2-4 and 20 as it depends from 2-4 are drawn to vectors as above that also include a portion of the *gag* gene to enhance packaging. One of ordinary skill in the art would have known from the combined teachings to modify the recombinant retroviral vectors suggested by Temin and Cone et al. by including a portion of the *gag* gene to ensure efficient packaging as suggested by Bender et al. Therefore, the invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

6. Claims 9 and 20 are rejected under 35 U.S.C. § 103 as being unpatentable over Temin in view of Cone et al. as applied to claims 1, 6-8, 20 and 21 above, and further in view of Kenten et al. or Kuo et al. Temin and Cone et al. are described *supra*. Kenten et al. describe the construction of various plasmid vectors for expression of foreign genes in myeloma cell lines. The

reference demonstrates the vector-mediated transfer of the gene for tissue plasminogen activator (tPA), under the control of a retroviral LTR promoter, into mammalian cells. Kuo et al. describe the cloning and expression in *E. coli* of Factor VIIIC. At page 34, the transfer of the gene into mammalian cells by way of retroviral vectors is suggested. Claims 9 and 20 as it depends from claim 9 are drawn to retroviral vectors carrying genes for factor VIII or tPA. The combined teachings of the prior art suggest the usefulness of expression of these proteins in mammalian cells in culture. The prior art of either Kenten et al. or Kuo et al. suggest expression of such genes by vector mediated gene transfer. The use of retroviral vectors would have been obvious, especially in view of the suggestions of Kenten et al. and Kuo et al. to use retroviral LTRs as promoters and the statement by Temin, cited above, that there "are no reports of genes that cannot be expressed in retrovirus vectors." Therefore the invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

7. Claims 10, 11, 17, 18 and 20 are rejected under 35 U.S.C. § 103 as being unpatentable over Temin in view of Cone et al. as applied to claims 1, 6-8, 20 and 21 above, and further in view of Emerman et al. Temin and Cone et al. are described *supra*. Emerman et al. describe the construction of retroviral vectors in which an internal heterologous α-globin promoter and 5' untranslated region is used to express the heterologous thymidine kinase gene. Claims 10, 11, 17, 18 and 20 as it depends from any of the preceding, are drawn to recombinant retroviral vectors which contain the α-globin promoter and 5' untranslated region. Emerman et al. teach the use of such a promoter construct to express a heterologous gene from a retroviral vector. It would have

been obvious to one of ordinary skill in the art to use such promoter constructs in the vectors of Temin, given the combined teachings of the prior art.

8. Claims 16 and 20 are rejected under 35 U.S.C. § 103 as being unpatentable over Temin in view of Cone et al. and Emerman et al. as applied to claims 10, 11, 17, 18 and 20 above, and further in view of Yee et al. or Yu et al. Temin, Cone et al. and Emerman et al. are as described above. Yee et al. and Yu et al. describe the modification of retroviral vectors for the purpose of deleting the 3' LTR enhancer or promoter sequences. These vectors are termed "disabled retroviral vectors" or "self-inactivating retroviral vectors". The intent is to prevent the activation of downstream genes by the 3' LTR when the retrovirus inserts into the host genome. Or, the inactivated elements may transfer to the 5' LTR, inactivating the enhancer in the 5' LTR, and thereby allowing regulated expression of a heterologous gene from an internal promoter without interference by expression from an active 5' LTR. Claims 16 and 20 as it depends from 20 are drawn to further modifications of the retroviral vectors of the instant application such that the retroviral enhancer element is inactivated such that the α-globin gene promoter controls the expression of the inserted heterologous gene. Given the combined teachings of the prior art, inactivation of the retroviral enhancer would have been obvious for allowing specific expression through the heterologous promoter.

9. Claim 19 is rejected under 35 U.S.C. § 103 as being unpatentable over Temin in view of Cone et al. and Emerman et al. as applied to claims 10, 11, 17, 18 and 20 above, and further in view of Kenten et al. or Kuo et al. Temin, Cone et al., Emerman et al., Kenten et al. and Kuo et

al. are as described above. Claim 19 is drawn to retroviral vectors which express either factor VIII or tPA. For essentially the same reasons as set forth hereinabove, the combined teachings of the prior art teaches the importance of expressing these proteins. It would have been obvious to express either factor VIII or tPA by way of such retroviral vectors.

10. Claims 12-15, 20 and 22 are rejected under 35 U.S.C. § 103 as being unpatentable over Temin in view of Cone et al. and Emerman et al. as applied to claims 10, 11, 17, 18 and 20 above, and further in view of Anderson and deVilliers. The teachings of Temin, Cone et al. and Emerman et al. are as described above. Anderson describes retroviral vectors for expression of exogenous genes. On pages 405-407, methods for optimizing and modifying the expression of exogenous genes are noted. In particular, the use of exogenous enhancers is described therein. deVilliers describes in Column 1, lines 32-53, the use of enhancers, specifically the CMV enhancer, to optimize the expression of exogenous genes inserted into vectors. Claims 12-15, 20 as it depends from 12-15, and 22 are drawn to retroviral vectors in which an exogenous enhancer is included to express heterologous genes. The combined teachings of the prior art suggest the use of exogenous enhancers, and particularly the CMV enhancer, for the same purpose. It would have been obvious to include such enhancers for this purpose.

11. Claim 22 is rejected under 35 U.S.C. § 103 as being unpatentable over Temin in view of Cone et al. as applied to claims 1, 6-8, 20 and 21 above, and further in view of Anderson or deVilliers. The teachings of Temin, Cone et al., Anderson and deVilliers are as presented above. Claim 22 is drawn to a defective recombinant retroviral vector based on a murine leukemia virus,

wherein the vector contains an exogenous enhancer. For the reasons set forth above, the use of exogenous enhancers as suggested by Anderson or deVilliers in the vectors of Temin taken with Cone et al. would have been obvious.

12. Claims 23 and 24 are rejected under 35 U.S.C. § 103 as being unpatentable over Temin in view of Cone et al., Anderson and deVilliers as applied to claim 22 above, and further in view of Hilberg et al. or Holland et al. The teachings of Temin, Cone et al., Anderson and deVilliers are as presented above. Hilberg et al. teach that retroviral vectors based upon Moloney murine leukemia virus (MuLV) may be generated which contain the enhancer region from a myeloproliferative sarcoma virus (MPSV) mutant. Substitution of this enhancer in the vectors of Temin taken with Cone et al. would have been obvious, particularly in view of the teaching that the use of the MPSV enhancer allows expression of the viral vector genome in embryonal carcinoma cells, a developmental cell line. Holland et al. teach that retroviral vectors based upon Moloney murine leukemia virus (MuLV) may be generated which contain the enhancer region from Friend murine leukemia virus (Fr-MuLV). Substitution of this enhancer in the vectors of Temin taken with Cone et al. would have been obvious, particularly in view of the teaching that the use of the Fr-MuLV enhancer allows expression of the viral vector genome in hematopoietic progenitor cells.

13. Claims 25-31, 40 and 41 are rejected under 35 U.S.C. § 103 as being unpatentable over Temin in view of Cone et al., Anderson and deVilliers taken with either Hilberg et al. or Holland et al. as applied to claims 23 and 24 above, and further in view of either Franz et al. or Weiher et

al. Temin, Cone et al., Anderson, deVilliers, Hilberg et al. and Holland et al. are as described *supra*. Weiher et al. teach that the B2 mutation of MuLV vectors works synergistically with the enhancer element and allows for enhanced RNA stability in certain cells, such as F9 cells. The discussion suggests that the B2 mutation may affect the efficiency of translation as well. Inclusion of the B2 mutation in the vectors of Temin taken with Cone et al., Anderson, deVilliers and either Hilberg et al. or Holland et al. would have been obvious as a means of increasing gene expression with these vectors. Franz et al. teach that retroviral vectors using MPSV LTRs can result in expanded host range of the vectors, especially in efficient transduction of embryonic cells. Inclusion of these LTR elements would have been obvious as a means of increasing the host range of the MuLV based vectors.

Response to Arguments

14. Applicant's arguments filed September 18, 1997 have been fully considered but they are not persuasive.

Applicant's first argument is that the particular vectors are not obvious over the claims of application No. 08/486,858 nor or the other claims obvious. Applicant does not, however, provide any reasoning to support this position. In the absence of any arguments or submission of a terminal disclaimer, this rejection is maintained.

Applicant then argues the 103 rejection. Applicant first argues that the Declaration of Lawrence Cohen overcomes the rejection. As previously stated the Declaration under 37

CFR 1.132 filed October 15, 1996 is insufficient to overcome the rejection of the claims based upon 35 U.S.C. 103 as set forth in the last Office action because:

The Declaration states that subsequent studies showed that the retroviral titers of Cone were insufficient to effectively transduce mammalian cells without selection and cites the Jaffee reference to support this assertion. No specific statement was found in the Jaffee reference indicating the titer of the retrovirus used. This reference, therefore, provides no evidence regarding the lack of reasonable expectation of success.

A second point regarding this argument relates to the differing methodologies utilized between the Jaffee and Cone references. The Jaffee reference transduces using 5×10^5 tumor explant cells and 10 mls of the retrovirus solution (no titer is given) (page 2222, column 1, paragraph 4). The Cone reference transduces using 1×10^5 cells with titers as high as 2×10^5 cfu/ml (page 6349, column 2, paragraph 4 and page 6350, column 2, paragraph 3). Thus, from the evidence in the papers, it is unclear whether the tenfold difference in the titer stated by the Declaration to be the minimal effective titer in fact relates to true differences in titer, or is simply related to the Jaffee use of 10 mls and the Cone use of 1 ml of virus.

The next argument in the declaration relates to the time period after Cone was published. Contentions that the references are old are not impressive absent a showing that the art tried and failed to solve the same problem notwithstanding its presumed knowledge of the references. *In re Wright*, 569 F.2d 1124, 193 USPQ 332 (CCPA 1977).

The Declaration, therefore, is given some weight in determining the obviousness of the claims. It is insufficient, however, because no factual evidence of a direct comparison between Cone and the invention is presented.

Applicant further argues the patentability of the specific vector constructs of claims 38-41. Claims 38-41 are not limited to specific constructs but are drawn to retroviral vectors having "the idenfying characteristics of ATCC 68,754 (claim 38)". Such vectors represent structural homologs or equivalents to those of claim 1. In the recent court decision *In Re Deuel* 34 USPQ 2d 1210 (Fed. Cir. 1995), the court determined that the existence of a general method of identifying a specific DNA does not make the specific DNA obvious. Regarding structural or functional homologs such as those discussed here, however, the court stated

> "Normally, a *prima facie* case of obviousness is based upon structural similarity, i.e., an established structural relationship between a prior art compound and the claimed compound. Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties (34 USPQ 2d 1210, 1214)."

Since the claimed vectors simply represent structural homologs, which are suggested by the prior art as useful for vectors, and concerning which a biochemist of ordinary skill would attempt to obtain alternate compounds with improved properties, the claimed vectors are *prima facie* obvious over the cited references in the absence of secondary considerations.

Applicant then repeats the argument that the Cone reference is not enabling based upon the Cohen Declaration. First, the reasons for the finding that the Cohen declaration was not convincing are given above. Second, as stated previously, The argument relating to the absence of a reasonable expectation of success is further weakened when one notes that Cone expressly states that success is expected "These titers are high enough to facilitate the nonselective introduction of genes into 100% of a population of cells at high enough cell numbers to allow rapid analysis of DNA, RNA, or protein (page 6353, column 1, paragraph 2)". Such an express statement that success would be expected meets the requirement of a reasonable expectation of success. The MPEP 2143.02 states

> "Obviousness does not require absolute predictability, however, at least some degree of predictability is required. Evidence showing there was no reasonable expectation of success may support a conclusion of nonobviousness. In re Rinehart , 531 F.2d 1048, 189 USPQ 143 (CCPA 1976) (Claims directed to a method for the commercial scale production of polyesters in the presence of a solvent at superatmospheric pressure were rejected as obvious over a reference which taught the claimed method at atmospheric pressure in view of a reference which taught the claimed process except for the presence of a solvent. The court reversed, finding there was no reasonable expectation that a process combining the prior art steps could be successfully scaled up in view of unchallenged evidence showing that the prior art processes individually could not be commercially scaled up successfully.). See also Amgen, Inc. v. Chugai Pharmaceutical Co ., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir.), cert. denied , 502 U.S. 856 (1991) (In the context of a biotechnology case, testimony supported the conclusion that the references did not show that there was a reasonable expectation of success. 18 USPQ2d at 1022, 1023.); In re O'Farrell , 853 F.2d 894, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988) (The court held the claimed method would have been obvious over the prior art relied upon because one reference contained a detailed enabling methodology, a

> suggestion to modify the prior art to produce the claimed invention, and evidence suggesting the modification would be successful.). "

There is no evidence of record submitted by applicant demonstrating the absence of a reasonable expectation of success. There is evidence in the Cone reference of the enabling methodology, the suggestion to modify the prior art, and a statement that the modification would be successful. The statement that Cone is wrong is not based on a factual analysis of the Cone reference as noted in the response to the Declaration above and is an unsupported assertion.

Applicant next argues that the invention is patentably distinct from the cited prior art. In response to applicant's arguments against the references individually, one cannot show non-obviousness by attacking references individually where the rejections are based on combinations of references. *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Here, it is the combination of the references as discussed in the rejection which renders the claimed invention. In a 103 rejection, it is not necessary for a single reference to teach the entire invention, rather it is the combination of references combined, with proper motivation, which must teach the invention.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596

(Fed. Cir. 19880; *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Cone provides specific motivation to perform transduction without a selectable marker stating "These titers are high enough to facilitate the nonselective introduction of genes into 100% of a population of cells at high enough cell numbers to allow rapid analysis of DNA, RNA, or protein (page 6353, column 1, paragraph 2)". This statement represents express motivation to perform nonselective transduction in order to permit rapid analysis of DNA, RNA or protein without necessitating the use of chemicals which might alter the experimental system. Further, Bender states "We conclude that the retrovirus packaging signal extends into the gag region. We have found that retroviral vectors containing the complete packaging signal allow more efficient gene transfer into a variety of cell types (page 1639, abstract)". This statement expressly motivates the use of such an inclusion of part of the gag sequence in order to permit more efficient gene transfer into a variety of cell types.

Applicants final argument is that the claimed invention provides unexpectedly superior results. The MPEP 716.02(b) states "The evidence relied up should establish "that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance." Ex parte Gelles , 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992)." Further, the MPEP 716.02 (d) states "Whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support." In other words, the showing of unexpected results must be reviewed to see if the results occur over the entire

claimed range. In re Clemens , 622 F.2d 1029, 206 USPQ 289, 296 (CCPA 1980)." In this instance, the applicant has not provided any evidence probative of unexpected results. Further, applicant's claims are not limited to any unexpectedly superior property. Evidence of unexpected results or other secondary considerations may be probative in this case.

Conclusion

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeff Fredman, Ph.D. whose telephone number is (703) 308-6568.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 180 by facsimile transmission via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center numbers for Group 1800 are either (703) 305-3014 or (703) 308-4242. Please note that the faxing of such papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Jeffrey Fredman, Ph.D.

November 5, 1997

W. GARY JONES
SUPERVISORY PATENT EXAMINER
GROUP 1800

11/6/97